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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,815	08/25/2004	Lars Lidgren	CU-3808 RJS	7180
26530 7590 01/30/2007 LADAS & PARRY LLP 224 SOUTH MICHIGAN AVENUE SUITE 1600 CHICAGO, IL 60604			EXAMINER LAURITZEN, AMANDA L	
			ART UNIT 3737	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			01/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/500,815

Applicant(s)

LIDGREN, LARS

Examiner

Amanda L. Lauritzen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 20 Aug 2004, 8 Dec 2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Priority***

1. Receipt is acknowledged of a certified copy of PCT/SE03/0045 filed 15 January 2003 referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

***Claim Objections***

2. Elimination of multiple dependent claims has resulted in many limitations lacking antecedent basis; for example, claim 8 recites, "the signal receiving or signal sending unit" and

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claim 10, "wherein the diagnostic camera is an X-ray camera". Please amend these claims and check for others so that antecedent basis is provided for all limitations.

3. The phrase "such as" in claim 29 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-25 and 27 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-19 of copending Application No. 10/333,159. This is a provisional double patenting rejection since the conflicting claims have not been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application

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since the referenced copending application and the instant application are claiming common subject matter, as follows: therapeutic ultrasound treatment of nucleus pulposus of a vertebral disc guided by optical imaging. The instant claims are broader in scope and are therefore anticipated by the copending claims. The instant claims are broader in that they do not claim attaching to the spinous process of the vertebra.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6, 8-10, 15-18, 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Hynynen et al. (US 2002/0151777).

Hynynen discloses an ultrasonic device for non-invasive treatment, wherein the transducer comprises multiple phased array elements for varying the focal length of the ultrasonic energy (paras. 11-12 and 59 in which the focus is varied by power and phase adjustment). The therapy includes non-invasive heating of the target tissue area (para. 14) and determination of tissue thickness and acoustic properties (Figs. 2 and 5 in which the depth of the tissue is determined; paras. 13-14). The therapeutic procedure is disclosed as “guided through imaging with MRI, CT, or diagnostic ultrasound” (para. 52). The positioning system inherently includes position sensors or transmitters and is disclosed with a control system that is operated either manually or automatically (para. 75). The system disclosed by Hynynen is capable for

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non-invasive heating of the vertebra for treatment of nucleus pulposus of the disc(s), as well as treatment of ligaments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hynynen.

Hynynen discloses all features of the invention as substantially claimed but states that the ultrasonic transducers of the device are not optimal for cardiac sonification but that “smaller transducers positioned manually by the surgeon on the epicardium can be easily designed and constructed” (para. 67). It would have been obvious to modify the system of Hynynen to include a “catheter based applicator delivered onto the heart via blood vessels” (para. 67) in order to treat internal structures.

7. Claims 7, 10-13, 20-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hynynen in view of Ishibashi et al (US 6,267,734).

Hynynen discloses all features of the invention as substantially claimed but is silent regarding use of a fixed-position reference device and an X-ray camera including markers to determine the position of an anatomical structure for viewing the treatment area. In the same field of endeavor, Ishibashi discloses use of an X-ray imaging system with markers (col. 33, lines 10-14; col. 39, lines 51-63) and a reference line (col. 21, lines 40-46). It would have been

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obvious to one of ordinary skill in the art at the time of invention to modify the system of Hynynen to include markers in order to indicate the treatment region in the image in the determined size and determined position (for motivation, see Ishibashi col. 33, lines 12-14) along with a reference line as taught by Ishibashi for the purpose of monitoring deviations of the shockwaves relative to a fixed position (Ishibashi, col. 21, lines 43-45).

Regarding claim 11, Ishibashi discloses tracking a diseased part "by taking the difference between two successive frames of the diagnostic image" (Fig. 19; col. 22, lines 40-42). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate top X-ray photographs of an anatomical structure for the purpose of locating a diseased section of tissue (col. 22, lines 40-44).

Regarding claim 20 and 25, the system of Hynynen as modified with the reference device of Ishibashi is capable of being attached to a vertebra in the patient's vertebral column for treatment of nucleus pulposus of the disc(s), as well as a ligament in a shoulder or knee.

Regarding claim 21, use of metallic tantalum balls are well known within the X-ray arts and it would have been obvious to use them to mark or reference.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

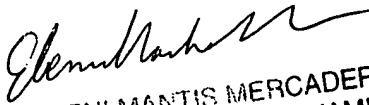
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



A.L.L.  
1/19/2007



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